K041059

510(k) Summary

5/17/05

Applicant Name
Dermagenics, Inc.
Steve Monroe, Ph.D.
3251 Poplar Avenue, Suite 150
Memphis, TN 38111
Phone: (901) 452-2395
Fax: (901) 452-3885

Date Prepared
April 22, 2004

Trade Name
Epi-Max®

Common Name
Sterile, non-adhesive wound dressing

Classification Name
Dressing (General and Plastic Surgery)

Substantial Equivalence

Predicate Device Name	510(k) Number
Johnson & Johnson Petrolatum Gauze Non Adhesive Dressings	K862163
Kendall Xeroform Petrolatum Gauze	K973507
CURASALT Hypertonic Saline Dressing	K942459
Kerlix Zinc Saline Dressing	K944468

Device Description
Epi-Max is a cellulose acetate mesh wound dressing (initially in a 2 x 3 in^2 size but later with smaller or larger sizes as per market demand) impregnated with 20mg of a petrolatum (polyethylene glycol-based) ointment. This ointment is a blend of PEG 400, PEG 4000, citric acid, a mild proprietary saline solution, and benzoic acid. The ointment is formulated to melt at skin temperature, helping to keep the wound moist and prevent wound-bandage adherence in order to make removal of the wound dressing less painful. Dressings are gamma irradiated for sterility.

Indications for Use
Epi-Max is indicated for use as a primary contact layer in dressing wounds such as lacerations, skin graft recipient sites, newly sutured wounds, abrasions, and minor or partial thickness burns. It may also be used as an initial layer in dressing surgical wounds with light exudates where mild medication and deoderization are desired.

Predicate Devices
Epi-Max is very similar to numerous other non-adhesive petrolatum gauze dressings and wet saline dressings previously approved by the FDA.

Instead of exclusively using either a petrolatum ointment or saline on the gauze, Epi-Max's ointment is a blend of USP-grade polyethylene glycols (PEGs) and a mild, proprietary saline solution buffered with USP-grade citric acid and with USP-grade benzoic acid added as a preservative. This blended ointment is designed to melt at skin temperature when applied to a wound, thus helping to promote a moist wound environment and making the dressing removal process easier and less painful.

Epi-Max's indications for use are identical to the indications for use made by Kendall Healthcare Products, inc. for their *Kendall Xeroform Petrolatum Gauze* dressings.

Non-clinical Performance Data
Epi-Max has been found to be non-cytotoxic, not a dermal irritant, and has a 0% sensitization rating using GLP studies based upon guidelines presented in the 10993 ISO Standard.

Clinical Performance Data
N/A

Non-clinical and Clinical Conclusions
Epi-Max is safe for human use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 17 2005

Steve Monroe, Ph.D.
Vice President – Technology
Greystone Medical Group
3251 Poplar Avenue, Suite 150
Memphis, Tennessee 38111

Re: K041059
Trade/Device Name: Epi-Max Impregnated Wound Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 22, 2005
Received: April 22, 2005

Dear Dr. Monroe:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Miriam C. Provost, Ph.D.
Acting Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K041059

Indications for Use

510(k) Number (if known): K041059

Device Name: Epi-Max Impregnated Wound Dressing

Indications For Use: For use as a wound dressing to manage pressure ulcers (stages I-IV), stasis ulcers, diabetic skin ulcers, skin irritations, cuts, and abrasions.

Prescription Use ✓ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

[signature]

[illegible] Restorative
[illegible] Devices

K041059